DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 14, 2015

AbbVie Inc.
Katherine Wortley
Director Regulatory Affairs
1 N. Waukegan Road
North Chicago, IL 60064

Re: K142793
Trade/Device Name: AbbVie PEG
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: January 9, 2015
Received: January 12, 2015

Dear Katherine Wortley,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142793

Device Name: AbbVie PEG

Indications for Use:

The AbbVie PEG is intended to provide long-term enteral access for administration of medication to the small intestine when used in conjunction with the AbbVie J, intestinal tube. As needed, enteral nutrition may be administered directly to the stomach in parallel with medication delivery to the intestine. The AbbVie PEG is indicated for the administration of the medication DUOPA (carbidopa and levodopa enteral suspension).

Prescription Use _X____	AND/OR	Over-The-Counter Use ____
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

SUBMITTER

AbbVie Inc.
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Contact Person: Katherine Wortley, Ph.D., Director Regulatory Affairs
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Date Prepared: September 25, 2014

DEVICE

Name of Device:	AbbVie PEG
Common or Usual Name:	Gastrostomy Tube
Classification Name:	Tubes, Gastrointestinal and Accessories (21 CFR 876.5980)
Regulatory Class:	II
Product Code:	KNT

PREDICATE DEVICE

AbbVie PEG, K133087
No reference devices were used in this submission.

DEVICE DESCRIPTION

The AbbVie PEG is a percutaneous endoscopic gastrostomy (PEG or gastric) tube, either 15 FR (List Number 62910) or 20 FR (List Number 62912) and 35 cm in length.

The product components include the following:

- AbbVie PEG Tube (polyurethane)
- External Fixation Plate (silicone, radio-opaque) with integrated Tube Clip and
- Tube Clamp.

Additionally, the kit includes the following components:

- Reel of thread
- Introducer device
- Puncture cannula with safety (air) valve and
- Disposable scalpel.

The kit is supplied sterile (ethylene oxide).

The AbbVie PEG is intended to allow the introduction of the AbbVie J intestinal tube for administration of medication in a home and/or healthcare facility environment. The AbbVie PEG is inserted through an incision in the abdominal wall over the stomach. The AbbVie J intestinal tube is placed through the PEG in order to deliver medication to the small intestine.

INDICATIONS FOR USE

The AbbVie PEG is intended to provide long-term enteral access for administration of medication to the small intestine when used in conjunction with the AbbVie J, intestinal tube. As needed, enteral nutrition may be administered directly to the stomach in parallel with medication delivery to the intestine. The AbbVie PEG is indicated for the administration of the medication DUOPA (carbidopa and levodopa enteral suspension).

COMPARISON OF TECHNILOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed device is identical to the predicate device (AbbVie PEG, K133087) with the exception of the proposed indication for use with DUOPA.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the AbbVie PEG was conducted in accordance with the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'* published May 1, 1995, *FDA Draft Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* published April 23, 2013 and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process,* as recognized by FDA. A gastrostomy tube is considered an external communicating device through tissue contact, with contact duration greater than 30 days. The battery of testing included the following:

- Cytotoxicity
- Sensitization
- Irritation (intracutaneous reactivity)
- Systemic toxicity (acute)
- Subchronic Toxicity (subacute toxicity)
- Pyrogen Testing
- Genotoxicity and
- Implantation.

Product Specific Performance Testing

The AbbVie PEG was assessed for conformance to standard EN 1615:2000 *Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing*. An assessment of the AbbVie PEG has been completed and shown to be acceptable per ISO 80369-1:2010 *Small-bore Connectors for Liquids and Gases in Healthcare Applications- Part 1: General requirements*. Food contact testing was conducted on the AbbVie PEG and demonstrated that the materials that constitute the AbbVie PEG are acceptable for food contact use. The study was conducted as described in 21 CFR 177.2600 *Indirect Food Additives: Polymers, Rubber articles intended for repeated use* per the extractable limits.

Animal and Clinical Studies

No animal or clinical evaluations were performed or relied upon for the determination of substantial equivalence.

CONCLUSIONS

The AbbVie PEG is an acceptable conduit for the AbbVie J and for delivery of nutritional materials to the stomach. The proposed device, AbbVie PEG, is substantially equivalent to the predicate device as it is identical to the previously cleared predicate device (AbbVie PEG, K133087). The indication for use with DUOPA does not alter the intended use (enteral delivery of fluids) or introduce a difference that impacts safety or effectiveness of the device.